UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS
PEORIA DIVISION

LATOYA THOMPSON,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	**Civil Action No.: 1:15-cv-01117-JES-JEH**
BAYER HEALTHCARE	)	
PHARMACEUTICALS INC.,	)	
BAYER PHARMA AG, and	)	
BAYER OY ,	)	
	)	
Defendants.	)	

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE OPINIONS OF REGULATORY EXPERTS DENA R. HIXON, M.D. AND DAVID W. FEIGAL JR., M.D.

Despite the Bayer Defendants' representation in related actions that they would narrow their expert witness list before *Daubert* motions were due in related actions, the Bayer Defendants never did so; Bayer still offers two different "regulatory experts" (Dr. Dena R. Hixon and Dr. David W. Feigal) who essentially offer many of the same regulatory opinions. *See* Hixon Report, attached as Ex. A; Feigal Report, attached as Ex. B; Hixon Deposition, attached as Ex. C; Feigal Deposition, attached as Ex. D. Nevertheless, the Bayer Defendants have promised in another similar case that they "do not intend to violate the court rules on presenting cumulative testimony at trial." *See* Ex. E. However, the Bayer Defendants fail to reveal (or, for that matter, even give any hints) which regulatory expert will be testifying in support of which opinions, flouting the spirit of both FRCP 1 and FRE 403. Nonetheless, the Bayer Defendants' strategy is pretty clear – double the chances that at least one of the two experts' opinions pass *Daubert* muster. If some of Feigal's opinions get excluded, no big deal; they still have Hixon. If some of Hixon's opinions get excluded, no big deal; they still have Feigal. Such a strategy is not only unfair; it also burdens both the Plaintiff and the Court by utilizing valuable, but scare resources.

Federal Rule of Evidence 702 requires an expert witness to testify as to "scientific, technical, or otherwise specialized knowledge." As the Supreme Court noted in *Daubert*, this requirement establishes a standard of "evidentiary reliability." *United States v. Hill*, 818 F.3d 289, 296 (7th Cir. 2016) (citing *Kumho Tire*, 526 U.S. at 149) (quoting *Daubert*, 509 U.S. at 590). Generally, for an expert's testimony to be admissible, "(1) the expert must be qualified, and (2) the subject matter of the expert's testimony must consist of specialized knowledge that will be helpful or essential to the trier of fact in deciding the case." *Myers v. Ill. Cent. R.R. Co.*, 679 F. Supp. 2d 903, 911 (C.D. Ill. Jan. 8, 2010) (quoting *United States v. Lanzotti*, 205 F.3d 951, 956 (7th Cir. 2000). The proffered expert's opinion must also be "(1) based upon sufficient

facts or data; (2) the product of reliable procedures or methods; and (3) applied reliably to the facts of the case." *Id*. (citing FRE 702).

It is the burden of the proffering party to establish the relevance and reliability of their experts' opinions. *See Daubert*, 509 U.S. at 592, n.10. "When evaluating whether an expert's testimony should be admitted, a court must consider whether the expert's testimony is 'supported by appropriate validation' and 'will assist the trier of fact to understand or determine a fact in issue.' *Hill*, 818 F.3d at 296 (quoting *Daubert*, 509 U.S. at 590-92; *Kumho Tire Co. V. Carmicheal*, 526 U.S. 137, 147 (1999)). The proponent of the expert testimony "bears the burden of demonstrating that the expert's testimony would satisfy the *Daubert* standard" and "that the pertinent admissibility requirements are met by a preponderance of the evidence." *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009) (internal quotation marks and citation omitted).

Courts must exclude expert opinions that are not "grounded in the scientific process." *Id*. (citing *Daubert*, 509 U.S. at 589-90; *Goodwin v. MTD Prods., Inc.* 232 F.3d 600, 608-09 (7th Cir. 2000)). An expert's opinion "may not be merely a subjective belief or unsupported conjecture." *Id*. Courts should "carefully vet[] expert testimony" and exclude this type of conjectural opinion testimony under Rule 403 because it "can be both powerful and quite misleading." *Hill*, 818 F.3d at 296 (internal quotation marks and citations omitted). "The reliability and relvance factors are designed to 'make certain that an expert, whether basing the testimony upon professional studies or personal experience employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Myers*, 679 F. Supp. at 912 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

Thus, under FRE 702, the "Court's role in determining the admissibility of expert testimony is that of a gatekeeper." *Ellis v. Pneumo Abex Corp.*, 62 F. Supp. 3d 833, 836 (C.D. Ill. July 30, 2014) (citing *Daubert* and *GE v. Joiner*, 522 U.S. 136, 142 (1997)). Thus, under *Daubert*, district courts have discretion to close the door to "junk science." *Id.* ("The principle of *Daubert*is merely that if an expert witness is to offer an opinion based on science, it must be real science, not junk science) (quoting *Tuf Racing Products, Inc. v. Am. Suzuki Motor Corp.*, 223 F.3d 585, 591 (7th Cir. 2000).

I. Dr. Hixon Should be Excluded as an Expert Because Her Opinions are Unreliable and Based on Faulty Foundations.

Hixon, a former FDA employee who was personally involved in the initial approval of Mirena, served as a regulatory expert in *In re: Mirena IUD Products Liability Litigation* MDL 2434 (the "Mirena MDL" or the "Migration/Perforation Cases"), subject to certain exclusions of her testimony, as discussed below. In sum, Hixon's opinions in the Mirena MDL concluded that the Mirena label, with respect to migration/perforation-type injuries, was adequate and that Bayer and its predecessors met or exceeded their regulatory responsibilities. For the first time, in February 2016 (the month before she prepared her report for this case), Hixon was hired to prepare a 37-page report in this case. Hixon Dep. 10:6-9. She even used "general sections" from her MDL report. *Id.* 13:5-18. In forming the opinions for her report regarding the appropriateness of Bayer's conduct, Hixon cited a single deposition of a non-US-based-Bayer entity employee. Yet, Hixon showed up at her deposition with a "Supplement List of Materials Reviewed" that newly ***eight*** depositions of current or former Bayer-associated employees, seven of which occurred prior to issuing her report.[1] Hixon admitted that she had not reviewed these

[1] Hixon also listed the deposition transcripts of three of Plaintiff's experts (Ross, Fraunfelder and Etminan on her supplemental list. *Id.* However, when questioned about them, Hixon revealed

depositions at the time she prepared her report. *Id.* at p. 69:14-19. When asked if she had reviewed them from beginning to end, Hixon testified that "some of them I did and some of them I didn't." *Id.* 20:10-15. Hixon struggled to name which depositions she reviewed in full, failing to even recall the names of the deponents without being provided with her own list of the names of the transcripts she allegedly reviewed. *Id.* 20:16-25, 21:1-11. In the end she admitted that, in deciding which of the transcripts she was actually going to review, that "I looked through them to see, you know, who they were and what the person's responsibilities were. And I read as many of them as I could get through." *Id.* 21:12-17.

As it relates to the Bayer's internal documents that ***Hixon*** herself listed in ***her report***, after initially testifying that she had reviewed "all" of the documents listed in her report (*Id.* 15:22-25, 16:1-2), she testified that she merely read the "vast majority" ... "[o]f all of the documents that I've listed." *Id.* 22:21-25. When asked how she decided which documents to review for purposes of this case, Hixon testified that she "made every attempt to review them all." *Id.* 23:1-4. With counsel knowing that there are well over 10 million pages of documents produced in this case, counsel followed up: "Q. Do you known how many documents – how many pages of documents have been produced in the benign intracranial hypertension cases? A. Thousands. Q. Just thousands? A. Well, probably hundreds of thousands." *Id.* 23:5-10.

Hixon admits that her "role" in this case "is purely as a regulatory expert, not as a causation expert or as a medical expert or any other role." *Id.* 74:15-25, 75:1-12. In the strictest sense, she is not an epidemiology expert, she is not a pharmacokinetics expert, and she is not an pseudotumor cerebri/intracranial hypertension ("PTC/IH") expert. *Id.* 75:13-18. But Hixon does correctly recognize that there is a difference between considering herself as an "expert" for

---

that she "reviewed Ross' deposition," "Fraunfelder to – to some extent," and "briefly looked at Etminan." Hixon Dep. p. 19:18-25, 20:1-9.

scientific purposes versus the legal standard for an expert and believes she fits the bill. *Id.* 75:19-25, 76:1-23.

But Hixon ventures outside of her "regulatory role" and makes various conclusory statements about the incidence rate of PTC/IH and its relation to obesity (*id.* at 79:15-25, 80:1-25) and the strength of "published studies" suggesting an association between "various drugs" and PTC/IH (*id.* at 78:16-25, 79:1-4). For both her information and her conclusions, Hixon allegedly relied on various studies cited in her report –but she was unable to cite the studies or even give basic information about the studies without reviewing a copy of her report. But even upon reviewing her report, she, to put it kindly, struggled with basic questions about the number of participants in the studies, the methods of the studies, the response rates, whether the studies had control groups, whether the studies controlled for confounders like drug usage, etc. *Id.* at 80:7-25, 81:1-25, 82:1-25, 83:1-25, 84:1-25, 85:1-25, 86:1-25, 87:1-25, 88:1-25, 89:1-25, 90:1-25, 91:1-25, 92:1-25, 93:1-25, 94:1-25. Hixon's excuse for her inability to discuss the details of the studies upon which she relied for her "strength" of association between drugs and PTC/IH, as well as obesity/overweight and PTC/IH, was "I have not committed those to memory. Sorry." *Id.* at 85:11-17; *see also id.* at 86:11-13 ("No, I have not committed them to memory."); 87:7-11 ("I have not committed that to memory."); 91:19-21 ("I have not committed that to memory."). True, it is unreasonable to expect an expert to memorize every detail (important or not) about every single material upon which they rely. But Hixon failed to demonstrate that she had ***any*** grasp of the very important details of the studies upon which she relied for her opinions about PTC/IH. Without knowing such details, not only are Hixon's opinions unreliable, but she has nothing to offer the jury in terms of helpfulness.

Moreover, indicative of the fact that Hixon is functioning as an advocate instead of an objective expert in this case is the fact that –in concluding that there is no evidence of an association between levonorgestrel and PTC/IH—Hixon fails to even acknowledge that Bayer's paid, non-testifying "consulting expert" has in fact written (before she was hired by Bayer, of course) that:

> **Among the many exogenous agents associated with intracranial hypertension, the best evidence exists for** the tetracyclines, vitamin A and retinoids, corticosteroid withdrawal, human growth hormone, nalidixic acid, leuprorelin acetate, chlordecone pesticide, **and levonorgestrel contraceptive system.**

See Deborah I. Friedman, MD, *Idiopathic Intracranial Hypertension*, Current Pain and Headache Reports 11:62-68 at p. 67 (2007) (emphasis added), attached as Exhibit F; *see also* Deborah I. Friedman, MD, et al., *The Pseudotumor Cerebri Syndrome*, Neurologic Clinics, Volume 32, Issue 2, pgs. 363-396 at p. 378, Box 3 (2014) (listing "Levonorgestrel (Norplant)" as an "associated" exogenous agent), attached as Exhibit G; Deborah I. Friedman, MD, et al., *Revised Diagnostic Criteria for the Pseudotumor Cerebri Syndrome in Adults and Children*, Neurology, Volume 81, pgs. 1159-65 at 1160 (2013) (identifying "levonorgestrel (Norplant System)" as a hormonal medication associated with "Secondary pseudotumor cerebri"), attached as Exhibit H; Deborah I. Friedman, MD, *Medication-Induced Intracranial Hypertension in Dermatology*, Am. J. Clin. Dermatol., Vol. 6, Issue 1, pgs. 29-37 at 30 (2005) (Table II lists "Medications associated with intracranial hypertension" and lists "Levonorgestrel implants" among them), attached as Exhibit I; Deborah I. Friedman, MD, *Doxycycline and Intracranial Hypertension*, Neurology, Volume 62 pgs. 2297-2299 at 2297 (2004) ("Intracranial hypertension (pseudotumor cerebri) is **associated with many exogenous agents** including … **levonorgestrel** … .") (emphasis added), attached as Exhibit J.

Hixon apparently was not provided with the Friedman articles by Bayer's lawyers; or, at least, Hixon failed to review them, rely on them, distinguish them, or even consider them. For one who wishes to testify that there is no evidence of an association or of a causal association (as Hixon purports to do), not considering this article (or numerous others that note the association between levonorgestrel and PTC/IH) is a serious fundamental failing that merits a wholesale exclusion of Hixon.

II. Hixon's Attempt to Perform a Reanalysis of the Initial Mirena Approval and Subsequent Heavy Menstrual Bleeding Indication Based Upon "Summary Reports" of FDA Employees Fails For Lack of Reliability.

Defendants have proffered Hixon as one of two "regulatory" experts. Hixon purports to offer six opinions (supported by a 37-page report) in this case:

Hixon Opinion 1

> It is my opinion that Bayer and its predecessors met or exceeded their regulatory responsibilities in the development of Mirena. They submitted adequate evidence of Mirena's safety and effectiveness to FDA to support approval of Mirena for five years of continuous use for pregnancy prevention and for the treatment of heavy menstrual bleeding for women who choose to use intrauterine contraception as their method of contraception.

Hixon Opinion 2

> In my opinion, Bayer followed FDA regulations for the Mirena labeling, including in its label all risks of Mirena for which there was reasonable evidence of an association.

Hixon Opinion 3

> In my opinion, Bayer appropriately collected and analyzed reports of adverse events and all available safety data from its clinical studies, postmarketing surveillance, and published literature, and reported that information to FDA in a timely manner.

Hixon Opinion 4

> In my opinion, Mirena is an important product for women's health with a favorable risk/benefit profile. The labeled risks of the product are far outweighed

by its superior effectiveness in preventing unintended pregnancy and the serious health risks that are associated with pregnancy and delivery or termination.

Hixon Opinion 5

In my opinion, there has never been a confirmed safety signal related to idiopathic intracranial hypertension in Mirena users. While a small number of IIH reports have been submitted to Bayer and FDA, the reporting rate is well below the expected rate of IIH in similar patients in the general population, even accounting for underreporting. Moreover, facts suggestive of a causal association are lacking.

Hixon Opinion 6

In my opinion, the Mirena label has always been adequate with respect to IIH. At no time before 2006 was there reasonable evidence of an association between Mirena and IIH. At no time since 2006 has there been reasonable evidence of a causal association between Mirena and IIH.

Hixon also sets out the bases for her opinions in the body of her report:

Basis for Opinions:

My opinions set forth in this report are expressed to a reasonable degree of medical and scientific certainty. I reserve the right to supplement these opinions if additional information becomes available, and I reserve the right to respond to the testimony of others. In forming my opinions, I relied upon my knowledge of the FDA regulations, policies and procedures, as well as my own training and clinical experience as an obstetrician/gynecologist providing women's health care, my experience at FDA as a medical officer generally,[2] and my experience

---

[2] Dr. Hixon's statement that she relied on her "experience at FDA as a medical officer generally" appears to be a reaction to her partial exclusion in the Mirena migration/perforation MDL due to her role as the "Mirena Team Leader" at the time of FDA approval in 2000. *See Danley v. Bayer (In re Mirena IUD Prods. Liab. Litig.)*, 2016 U.S. Dist. LEXIS 29752, *182-189 (S.D.N.Y. Mar. 8, 2016) ("Dr. Hixon's testimony relating to the FDA's review of Mirena's NDA in 2000 is thus excluded pursuant to Rule 37(c)(1) and in any event is also inadmissible under Rule 403." *Id.* at *189.) As the court noted, "Although Defendants argue that Dr. Hixon is not basing her testimony on her personal recollections regarding the Mirena labeling process, Plaintiffs are correct that (as Dr. Hixon conceded, (Hixon [MDL] Dep. at 134:23-135:2)) it would be impossible for a witness to divorce herself from her memories about what occurred during a project in which she was an active participant and segregate that information from the documentary record in forming her opinions." *Id.* at p. 183-84. "Defendants have not offered a reason why they chose Dr. Hixon as a regulatory expert when they knew she could not fully disclose the bases of her opinions. Plaintiffs should not be unfairly prejudiced because

> with following the regulations in making decisions regarding product approval, labeling modifications and other regulatory matters for a wide range of products.
>
> Hixon defined her "task in this case" this way at her deposition:
>
> Q. And what's your task in this case?
> A. Well, my task in this case was to review the documents relevant to the -- basically the approval of Mirena and the labeling of Mirena and the background on -- on use of the product, its risk-benefit analysis and IIH, and the information available about IIH, what is IIH and what may or may not cause IIH, and to develop opinions with regard to whether the labeling was adequate and whether the interactions with FDA were appropriate.

Hixon at p. 26, lines 2-11. In plain language, Dr. Hixon purports to review the original Investigational New Drug Application ("IND") and the New Drug Application ("NDA") for Mirena (as well as the supplements leading to Bayer's approval for a heavy menstrual bleeding indication) and conclude whether the Mirena label was (and still is) adequate and whether Bayer's interactions with FDA were at all times appropriate. She certainly possesses the regulatory qualifications to do so, but her opinions also stray into areas in which she is clearly not an expert either in the technical sense or within the relaxed context of FRE 702, particularly with respect to PTC/IH. While Hixon does indeed testify about regulatory-type issues, her

---

Defendants chose to retain an expert who participated directly in some of the events at issue but cannot discuss them." *Id.* at 187-88. The circumstances are similar in this case: a) Hixon's testimony involves the same product and the same 2000 FDA review, b) Hixon still cannot "divorce herself" from her personal involvement in the 2000 approval, c) Hixon, presumably, is still bound by the FDA's confidentiality policy to not disclose such conversations or memories about what occurred during the approval process; d) Bayer, even after the MDL court's ruling, offered Hixon as an expert in this case to testify to the same basic conclusions that she reached in the MDL (i.e., that the warning was adequate and that Bayer and its predecessors met or exceeded their regulatory responsibilities in the development of Mirena). "Moreover," as the MDL court noted, "a jury would likely afford Dr. Hixon's testimony added credence because she was present during the FDA's Mirena review and would be perceived as having inside information" *Id.* For the same reasons, this Court should also preclude Hixon from offering testimony related to the FDA's review of the Mirena New Drug Application that was approved in 2000 pursuant to both Rule 37(c)(1) and/or FRE 403.

attempts to undermine an association between levonorgestrel and PTC/IH are not grounded in reliable scientific methods, as discussed above.

As it relates to her pure regulatory opinions, in plain language, Hixon's first opinion essentially amounts to a complete reanalysis of both the initial product approval decision, as well as the approval of the heavy menstrual bleeding indication nearly a decade later, including whether Bayer met or exceeded their regulatory responsibilities" (she concludes Bayer did), whether Bayer acted appropriately with regard to communicating with FDA (she concludes Bayer did), "submitted adequate evidence of Mirena's safety and effectiveness to FDA" (she concludes Bayer did), and whether the product was appropriately labeled (she concludes it was). But Hixon's reanalysis rests entirely upon the "summaries" of the FDA employees who actually ***prepared*** the original analyses (by reviewing the underlying data) and her conclusion about what may or may not be "relevant" to those determinations.

For instance, in this case, Bayer has produced what is known as the company's Mirena IND/NDA file that contains all of the relevant documents sent to and from FDA regarding the Mirena product during the relevant time periods. Documents from this file are denoted with a bates label of "MIR_INDNDA_" or "MIR_INDNDA-R_" followed by eight digits. According to counsel's latest count, approximately 481,000 pages have been produced under the MIR_INDNDA_ label and another 326,796 under the MIR_INDNDA-R_ label. Yet, Hixon never reviewed the entire file. Not even close. In fact, from her materials list, it is readily apparent that she wasn't even given a small fraction of these documents. She certainly did not review the underlying pre-approval studies, any post-approval studies, the underlying pharmacological data, the underlying chemistry data, the underlying manufacturing and controls data, the underlying animal study data:

Q. Okay. So I'm talking -- you reviewed the NDA in this case, right?
A. I reviewed the parts of the NDA that I needed to review. No one at FDA reviews every page of the NDA.
Q. They don't?
A. No.
Q. Not even the team leader?
A. No.
Q. What parts of the NDA did you consider to be not relevant to your task in this case?
A. I think I already answered that question.
Q. Well, if it's only the underlining [sic] animal -- the raw data for the animal studies and the CMC information, then you have answered it. If there's anything else, I'm entitled to be able to find out.
A. Well, there is also all the raw data. I mean, all the raw data is analyzed in the study reports and it's reviewed at FDA and the information is summarized by the disciplines that are relevant to each section of the NDA. For purposes of, for instance, a team leader making a recommendation about approval of the product, no team leader is going to review every page of that NDA. A team leader would look at the reviews of -- the summary reviews of each individual discipline and go into any sections of the NDA that they needed to look at in order to reach their conclusion. Likewise, with the kind of task that I had before me here, that same sort of thing was the relevant information that needed to be reviewed, not to dig out every animal study, every piece of raw data from anything, but to get the overall big picture and look at the sections that are relevant to the question at hand.

Hixon Dep. 28:10-25, 29:1-21. *See also*:

Q. Which -- what parts of -- what parts of the NDA would you consider to be not relevant to your task in this case?
A. I think I already pointed out a lot of that. A lot of the CMC details would not make a difference in my opinion. A lot of the -- the raw data that's presented for animal studies and clinical studies is not relevant. The – the detailed sections of statistics and -- and all of the individual studies are not nearly as important to what I need to do as the overview and the FDA analysis of that material.

Hixon Dep. 26: 20-25, 27:1-6. *See also*:

Q. So you didn't -- in this case, for your task in this case, you didn't review any of the underlining [sic] raw data contained in the Mirena NDA?
A. As far as I can think right now, there --there wasn't any raw data that I needed to go back and look at.
Q. Okay. And I'm just trying to make sure that I'm understanding you correctly. So for purposes of this case and your analysis of the NDA, you

relied upon the individual reviewers who prepared their portions of the NDA?
A. That is largely true.
Q. Okay. How's it -- how's it not largely true?
A. Well, there are things that I might not remember sitting here right now that if -- when you ask me further questions, I may remember and need to discuss. But as far as the big picture of what we're talking about, I'm giving you the information that I can.
Q. Okay. Well, this is my only chance to ask you.
A. I understand that.

Hixon Dep. 29:22-25, 30:1-19. *See also*:

Q. And is it -- did I understand you correctly to say that all of the information in the NDA is not necessarily relevant to the task that you have in this case?
A. That's correct.
Q. Okay.
A. There are details -- many details that are not relevant.

See Hixon Dep. 26:12-19.

By her own admission, Hixon relied on the summaries of others to make her regulatory conclusions for this report. In her own words, Hixon merely reviewed what she deemed to be "relevant" to give her interpretation, relying almost exclusively on summary reports (or "overviews") and ignoring the underlying detail. She claims that as the "Team Leader for Mirena" at FDA when Mirena was originally approved, that is how she did her job. If so, that's sad. Nevertheless, Hixon should be held to a higher standard for her reanalysis, done without the benefit of being able to even communicate with the drafters of the overviews/summaries upon which she relies for her opinions in this case.

In essence, Defendants offer Hixon for the opinion that FDA rightfully approved Mirena in December 2000. In arguing that the FDA "got it right" and the Defendants "did it right," and indeed went well beyond the FDA's requirements. But such an opinion, as she phrases it, is impossible to support having relied only upon the summaries.

Moreover, with regard to whether Bayer's employees acted appropriately in investigating reports of PTC/IH, including conducting safety signal investigations, Hixon never even contacted a single Bayer employee --despite being the Defendants' expert witness and having full access to their employees. *Id.* 55:8-14.

If her opinions are not a "reanalysis" of the evidence submitted to the FDA at the time of the NDA and a "reevaluation" of FDA's decision making at the time, then her "opinions" add nothing new to assist the jury. But without reviewing the underlying clinical studies, literature, correspondence, labeling negotiations, etc., Hixon cannot and should not be allowed to opine that Bayer and its predecessors "met or exceeded their regulatory responsibilities," "submitted adequate evidence of Mirena's safety and effectiveness to FDA," that Mirena has a "favorable risk/benefit profile," or that Bayer "include[ed] in its label all risks of Mirena for which there was reasonable evidence of an association." Accordingly, the motion should be granted.

III. Feigal's Report is Similarly Deficient and His Testimony Should Be Excluded.

Like Hixon, Feigal is a former FDA employee who also served as a regulatory expert in the Mirena MDL[3] for the migration/perforation cases, subject to certain exclusions of his testimony, as discussed below. In sum, Feigal's opinions in the Mirena MDL concluded that the Mirena label, with respect to migration/perforation-type injuries, was adequate and that Bayer and its predecessors met or exceeded their regulatory responsibilities.

Like Hixon, Feigal claims that he was first contacted in February 2016 to provide his March 24, 2016 report. *Id.* 19:6-10. Like Hixon, Feigal has never bothered to talk with any Bayer employees. Feigal Dep. at 51:11-14. Like Hixon, Feigal showed up on the morning of his deposition with a "supplemental reliance list" claiming, among other things, to have reviewed

[3] In fact, Feigal did not even bother to change his cover/title page of his report to reflect *this* litigation; rather, it lists the name of the MDL.

eleven depositions ***after*** preparing his report. *Id.* 37:4-25; 38:1-7. Notably, seven of the eleven depositions had taken place long before his report was even due. *Id.* 37:24-25; 38:1-7. Nonetheless, like Hixon. Feigal did not read the full depositions either; instead, he claimed to have "familiarized myself with those depositions." *Id.* 37:4-23. Feigal could not even be sure that he reviewed the entirety of the ***single*** deposition provided to him by Bayer's lawyers before his report was due. *Id.* 36:2-14. "Sometimes," according to Feigal, he "use[s] the index to find key sections, so I just don't recall if I've read the entire thing." *Id.* 36:5-8.

Also, like Hixon, Feigal's report fails to address the fact that Bayer's consulting expert, Dr. Deborah Friedman, has written the several articles discussed above about the association between levonorgestrel/levonorgestrel contraceptive system/levonorgestrel implants/Norplant. The "Materials Reviewed" portion of Feigal's report claims that he reviewed a 2002 Friedman article called "Diagnostic Criteria for Idiopathic Intracranial Hypertension." Feigal Report, "Materials Reviewed" List at p. 4.[4] But Feigal fails to address the article in his report and does not recall it during the course of his deposition. Feigal Dep. 42:22-25, 43:1-16. Rather than acting as an objective expert, and carefully evaluating all sides of the evidence, Feigal's opinions are pure advocacy that are based upon a sloppy review of the evidence provided to him. Accordingly, his testimony should be excluded.

IV. Neither Feigal Nor Hixon Engaged in the Appropriate Analysis for a Causation Assessment Related to Levonorgestrel and PTC/IH.

Neither Feigal nor Hixon engaged in the proper Bradford Hill analysis in reaching their core opinions regarding whether or not Mirena can cause PTC/IH. Factors known as the "Hill

[4] The 2002 article, at table 3, notes "Conditions that may produce intracranial hypertension and masquerade as idiopathic intracranial hypertension" and lists the "Norplant levonorgestrel implant system" under the "medications" portion. *See* Deborah I. Friedman, et al., *Diagnostic Criteria for Idiopathic Intracranial Hypertension*, Neurology, Vol. 59 pgs. 1492-1495 at p. 1494, table 3 (2002), attached as Exhibit K.

criteria" or the "Bradford Hill criteria" are "helpful in determining whether a causal association from epidemiological evidence has occurred." *Rains v. PPG Indus.*, 361 F. Supp. 2d 829, 835 (S.D. Ill. Dec. 23, 2004). Stated succinctly, the criteria are: temporal relationship, strength of the association, dose-response relationship, replication of the findings, biological plausibility (coherence with existing knowledge); consideration of alternative explanations; cessation of exposure; specificity of the association; and consistency with other knowledge. *Cunningham v. Masterwear, Inc.*, 2007 U.S. Dist. LEXIS 29156, at *10 n.3 (S.D. Ind. Apr. 19, 2007). Those criteria "provide[] a useful framework to analyze the reliability of a causal association." *Rains*, 361 F. Supp. at 835. Indeed, some courts even go so far as to exclaim that "Bradford Hill factors are **essential** to evaluating the weight of epidemiological evidence . . ." *In re Actos (Pioglitazone) Products Liability Litigation*, 2014 WL 108923, *5 n. 31 (W.D. La. 2014) (emphasis added). While Hixon does not even mention the Bradford Hill factors, Feigal mentions them only in the context of attacking another expert's opinions. *See* Feigal Report at p. 48-50. In fact, according to Feigal, because he believes there is "no association" between levonorgestrel and PTC/IH, he thinks it is "inappropriate to even apply Bradford Hill's framework here." *Id.* at 48. Feigal's attacks on Plaintiff's experts, besides being curt, reflect a tone of ardent advocacy, versus the objective, independent analysis of the subject matter as envisioned by our rules.

V. Both Feigal and Hixon Attempt to Offer Improper Opinions About State of Mind, Motives and Intent.

Feigal and Hixon both attempt to offer opinions that suggest that FDA would not approve a Mirena label that includes an intracranial hypertension warning like the Norplant product did. But as the Mirena MDL court concluded, with regard to both Feigal and Hixon, neither should be permitted to testify as to what type of label the FDA would or would not ultimately accept or

reject. *Danley v. Bayer (In re Mirena IUD Prods. Liab. Litig.)*, 2016 U.S. Dist. LEXIS 29752, *169 (S.D.N.Y. Mar. 8, 2016). As the court held:

> "This is impermissible speculation as to the state of mind of the FDA. See Kruszka v. Novartis Pharms. Corp., 28 F. Supp. 3d 920, 931 (D. Minn. 2014) ("[The experts] may not proffer an opinion relating to what individuals . . . with the FDA thought with respect to certain documents or about their motivations."); Deutsch, 768 F. Supp. 2d at 442 (testimony on "intent, motives, or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise") (internal quotation marks omitted). Nonetheless, he may testify as to what the FDA did, and what it said, based on the documents he reviewed. Dr. Feigal based his opinion on documents that reflect communications between Bayer and the FDA, exchanged during multiple label approval processes spanning several years. (Feigal Report at 20-27.)
> …
> Dr. Feigal may not testify as to whether the FDA would have rejected or accepted a specific warning, and Plaintiffs' motion is thus granted with respect to such testimony.

Id. at 169-70. Likewise, with regard to Hixon, the MDL court held:

> As discussed in greater detail in connection with Dr. Feigal, expert testimony related to a company's or agency's state of mind, motives or intent is impermissible. See In re Rezulin, 309 F. Supp. 2d at 546. Dr. Hixon is not allowed to opine on an entity's intent or state of mind that is not "clearly indicated in public documents." In re Levaquin, 2011 U.S. Dist. LEXIS 149369, 2011 WL 6888533, at *2. Dr. Hixon will be permitted to testify to the same extent as Dr. Feigal. She may explain and opine on documents or communications between Bayer and the FDA and on public filings relating to Mirena (except to the extent I have already limited her admissible testimony under Rule 37(c) and Rule 403).
>
> In her report, Dr. Hixon wrote that the "FDA would not accept the words 'most often' in the Mirena perforation warning" in 2008. (Hixon Report at 41). Dr. Hixon may describe what language the FDA struck, what it said regarding why it struck that language, and what recommendations it made for Defendants to consider, but it will go too far (and is unnecessary) to say the FDA at that time "would not accept" that language under any circumstances. That the FDA "recommend[ed]" against using non-specific terms and suggested that Defendants "[c]onsider either no frequency qualifier or a frequency range," (Cook Hixon Decl. Ex. 10, at MIR_INDNDA_00038079), does not mean that it necessarily would have refused "most often" had Defendants pushed back or provided more information. Dr. Hixon may not opine on what type of label the FDA would have hypothetically accepted or rejected, as this is impermissible state of mind testimony. See Kruszka, 28 F. Supp. 3d at 931; Deutsch, 768 F. Supp. 2d at 442. Defense counsel may argue to the jury that the FDA's conduct in 2008 shows that

> it would not have accepted a warning regarding perforation after insertion, and Plaintiffs' counsel may argue to the contrary, and the jurors will decide what inference is justified. But experts will not draw that inference for them.

Id. at 189-91. For these same reasons, this Court should exclude all testimony by Feigal and/or Hixon related to "a company's or agency's state of mind, motives, or intent" because it is "impermissible" expert testimony.

CONCLUSION

For the foregoing reasons, Plaintiff's motion should be granted.

Respectfully submitted,
JONES WARD PLC

/s/ Lawrence L. Jones II

Lawrence L. Jones II
The Pointe
1205 E. Washington St., Suite 111
Louisville, Kentucky 40206
Tel: (502) 882-6000 | Fax: (502) 587-2007
larry@jonesward.com

Counsel for Plaintiff

CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies, in compliance with local rule 7.1(B)(4)(c), that the foregoing memorandum of law complies with the type volume limitation. The undersigned further certifies, in reliance upon the word count of the word processing system used to prepare the document, that the foregoing memorandum consists of 5,912 words, including headings, footnotes, quotations, and signature.

/s/ *Lawrence L. Jones II*
Lawrence L. Jones II

CERTIFICATE OF SERVICE

I hereby certify that on March 15, 2017, I served all counsel of record with the foregoing via this Court's CM/ECF System, which will provide notice of filing to all counsel of record.

/s/ *Lawrence L. Jones II*
Lawrence L. Jones II